

SOUTHWEST ONCOLOGY GROUP

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COMMUNITY CLINICAL ONCOLOGY PROGRAM GUIDELINES

The Southwest Oncology Group has developed the following guidelines for Community Clinical Oncology Programs (CCOPs) which have an interest in associating with the Southwest Oncology Group as a research base:

1. Each CCOP must submit an application to the National Cancer Institute (NCI) describing its organizational structure and governing body, and naming the Southwest Oncology Group as its research base. CCOPs without prior experience using Southwest Oncology Group protocols should describe their prior experience with national or local protocols.
2. Each CCOP must submit a Statement of Assurance to ensure that every protocol to be used by any physician affiliated with the CCOP will have prior approval by the appropriate hospital's Institutional Review Board (IRB). All patients must have given informed consent, in accordance with the National Cancer Institute and Southwest Oncology Group Guidelines, prior to registration and initiation of treatment. All informed consents will give permission for the patient's original hospital record to be reviewed, for quality assurance, by representatives of the NCI, the Southwest Oncology Group, and/or approved select drug monitors from the pharmaceutical industry involved in the protocol.
3. Physicians who are members of a group of practicing physicians or a consortium must identify the hospital(s) in which their patients will be treated to both the NCI and the Operations Office.
4. Every CCOP physician participating in Southwest Oncology Group protocol studies must have curriculum vitae on file in the Southwest Oncology Group Operations Office. An FDA 1572 (Statement of Investigator) and supporting documents must be submitted to the Pharmaceutical Management Branch (NCI) on an annual basis by all participating investigators. Other documentation may also be required for submission from new investigators.
5. Each CCOP will abide by rules and performance criteria governing all Southwest Oncology Group members in regard to patient eligibility, patient evaluability, timeliness of data submission, radiotherapy and pathology evaluability and quality control determination. The Southwest Oncology Group will provide for patient registration, Statistical Center data management, statistical analysis, and training of support personnel, quality control and quality assurance in accordance with Southwest Oncology Group policies.
6. Each CCOP physician will provide assurance of short and long term follow-up of all registered patients. All Southwest Oncology Group patients are followed long-term as specified in each individual protocol. Penalties for failure to meet this commitment may include suspension of registration, probation or termination of Southwest Oncology Group affiliation.
7. All CCOP members will be required to participate in Quality Assurance Audits as deemed necessary.

8. The Southwest Oncology Group Operations Office will provide assistance to proposed CCOP institutions in the preparation of their institutional applications for funding regarding the activities of the Group as the named Research Base. This assistance will include the provision of institutional performance evaluation results, accrual data, and the development and finalization of a CCOP Affiliation Agreement with that institution. The Group Chair also provides the funding agency, the Division of Cancer Prevention (DCP), with letters of recommendation for all proposed CCOP institutions.
9. Following approval of the institution's funding application, the Group Chair will submit a membership nomination for all new CCOP institutions to the Board of Governors. CCOPs recommended for approval by the Board of Governors will become probationary members of the Southwest Oncology Group for a period of up to, but not exceeding, 18 months. During the period of probation, the performance of the CCOP will be monitored by the Group Chair, Operations Office, and Statistical Center. The CCOP may be moved to full member status at any time during the probationary period once all criteria for full membership have been met.
10. All CCOP members (Probationary and Full Member) are eligible to attend the open scientific and administrative sessions of the Southwest Oncology Group semi-annual meetings. All CCOP member institutions are required to attend at least one Group Meeting every two years.
11. Each CCOP member at an institution approved for full membership is eligible, as is any Southwest Oncology member, for appointment to Disease Committees, Discipline Committees and Standing Committees. They are also entitled to participate in protocol design and coordination following the completion of the Southwest Oncology Group Study Coordinator Workshop.

CRITERIA FOR FULL MEMBERSHIP FOR CCOPS

In order to obtain full member status, the following criteria must be met:

1. Accrual of at least 50 evaluable patients.
2. A successful Quality Assurance Audit (usually performed after accrual of at least 30 patients).
3. Acceptable quality control standards in patient eligibility and data submission.

COMPLIANCE WITH FEDERAL REGULATIONS

Each CCOP must comply with all applicable federal regulations governing the conduct and monitoring of clinical trials, to include ensuring compliance with the Code of Federal Regulations (45 CFR 46, 21 CFR 50, and 21 CFR 56) in the protection of human subject research and Institutional Review Board review and approval of research studies and consent forms, conducting research in compliance with the ethical principles embodied in The Belmont Report (respect for persons, beneficence and justice), and ensuring the confidentiality of patient data (e.g., the Health Insurance Portability and Accountability Act – HIPAA). Non-compliance with federal regulations may result in investigation or censure